

## Senate Bill No. 1238

### CHAPTER 197

An act to amend Sections 3500 and 3502 of the Penal Code, relating to prisons.

[Approved by Governor August 25, 2016. Filed with  
Secretary of State August 25, 2016.]

#### LEGISLATIVE COUNSEL'S DIGEST

SB 1238, Pan. Inmates: biomedical data.

Existing law prohibits biomedical research, as defined, from being conducted on any prisoner in the state.

This bill would specify that biomedical research does not include the accumulation of statistical data in the assessment of the effectiveness of nonexperimental public health programs or treatment programs in which inmates routinely participate. The bill would authorize records-based biomedical research involving inmates that uses existing information, but which does not include prospective interaction with human subjects.

*The people of the State of California do enact as follows:*

SECTION 1. Section 3500 of the Penal Code is amended to read:

3500. For purposes of this title:

(a) "Behavioral research" means studies involving, but not limited to, the investigation of human behavior, emotion, adaptation, conditioning, and response in a program designed to test certain hypotheses through the collection of objective data. Behavioral research does not include the accumulation of statistical data in the assessment of the effectiveness of programs to which inmates are routinely assigned, including, but not limited to, education, vocational training, productive work, counseling, recognized therapies, and programs that are not experimental in nature.

(b) "Biomedical research" means research relating to or involving biological, medical, or physical science. Biomedical research does not include the accumulation of statistical data in the assessment of the effectiveness of nonexperimental public health programs or treatment programs in which inmates routinely participate.

(c) "Psychotropic drug" means a drug that has the capability of changing or controlling mental functioning or behavior through direct pharmacological action. These drugs include, but are not limited to, antipsychotic, antianxiety, sedative, antidepressant, and stimulant drugs. Psychotropic drugs also include mind-altering and behavior-altering drugs that, in specified dosages, are used to alleviate certain physical disorders, and drugs that are ordinarily

used to alleviate certain physical disorders but may, in specified dosages, have mind-altering or behavior-altering effects.

(d) “Research” means a class of activities designed to develop or contribute to generalizable knowledge, including theories, principles, or relationships, or the accumulation of data on which they may be based, that can be corroborated by accepted scientific observation and inferences.

(e) “Research protocol” means a formal document setting forth the explicit objectives of a research project and the procedures of investigation designed to reach those objectives.

(f) “Phase I drug” means a drug that is designated as a phase I drug for testing purposes under the federal Food and Drug Administration criteria in Part 312 of Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations.

SEC. 2. Section 3502 of the Penal Code is amended to read:

3502. (a) Biomedical research shall not be conducted on any prisoner in this state.

(b) Notwithstanding subdivision (a), records-based biomedical research using existing information, without prospective interaction with human subjects, may be conducted consistent with this title. The use or disclosure of individually identifiable records pursuant to this subdivision shall only occur after both of the following requirements have been met:

(1) The research advisory committee established pursuant to Section 3369.5 of Title 15 of the California Code of Regulations approves of the use or disclosure.

(2) The prisoner provides written authorization for the use or disclosure, or the use or disclosure is permitted by Section 164.512 of Title 45 of the Code of Federal Regulations.